TEST & CURE

The HCV Coalition Quarterly

Testing Update: HCV Testing Campaign Launches

Welcome to the First Edition of the HCV-TAC Quarterly Newsletter

On behalf of our HCV-TAC project team and our collaborating HCV-TAC Coalition partners, I'm pleased to introduce this first issue of our Coalition newsletter. With each issue we aim to provide brief summaries of clinically relevant topics in HCV care to improve the identification, testing, evaluation, treatment, and cure of persons with HCV. In this issue you will find summaries of HCV treatment availability, recommendations for routine use of antibody plus "reflex" NAT testing to screen for HCV infection, news from Project ECHO, and a new focused on-line HCV curriculum for clinicians that offers free CME credits. We hope you find this information useful in your clinical practice and welcome suggestions for future topics.

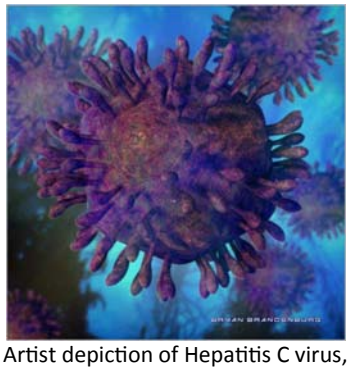
Sincerely,
Jeff Duchin, Health Officer & HCV TAC Project PI
Public Health – Seattle & King County

Public Health
Seattle & King County

Q3/15

The **Test & Cure** quarterly is a publication of the Communicable Disease Epidemiology & Immunization Section of Public Health.

Status of Hepatitis C Treatment Availability in Washington State



Artist depiction of Hepatitis C virus, Courtesy of Bryan Brandenburg

HCV medications Solvaldi (left) and Harvoni (right), Gilead Sciences. Photos: Andrew Karpenko, University of Washington; Hepatitis C Online

We are in the midst of a revolution in hepatitis C (HCV) treatment. For the first time in medical history we have an effective, easy to tolerate cure for a chronic, viral infection. Cure rates are approaching 100% and treatment has gone from 6-12 months of interferon-based therapy with very difficult side effects to 12 weeks of an all-oral regimen with minimal side effects for most people. Unfortunately, healthcare insurance providers, both private and public, are restricting access to these new therapies.

In a study published in June 2015 in the Annals of Internal Medicine, Dr. Lynn Taylor and colleagues evaluated state Medicaid policies for access to sofosbuvir-based HCV treatment. Taylor found that 74% of states restrict access to patients with advanced liver disease (F3 or greater fibrosis); 67% have restrictions based on prescriber type; 64% require drug urine screening; and 50% require a period of drug/alcohol

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Status of Hepatitis C Treatment Availability in Washington State (continued)

abstinence. These restrictions run counter to current treatment recommendation from the American Association for the Study of Liver Diseases and may, in fact, be illegal. "Current restrictions seem to violate federal Medicaid law, which requires states to cover drugs consistent with their U.S. Food and Drug Administration labels," the study authors wrote. Several groups, including Harvard's Center for Health Law and Policy Innovation, are exploring legal action that would seek to require states to expand access to treatment. Massachusetts fee-for-service Medicaid places no restrictions on access to treatment for HCV. The added benefit of this "no-restrictions" policy, in addition to ethical and legal considerations, is that Massachusetts Medicaid realizes a significantly larger supplemental rebate from the companies that manufacture HCV drugs.

In Washington State, we have seen some of the Medicaid restrictions related to HCV treatment access removed in the past year, including the removal of a blanket exclusion of anyone who has injected drugs in the past six months and slightly expanded access for individuals co-infected with HIV and/or hepatitis B. However, the Washington State Health Care Authority (HCA) still only pays for patients with stage 3-4 fibrosis, leaving a majority of patients without coverage of first line antivirals. The approval process is slow, taking >3 months on average.

Currently at the Harborview Hepatitis and Liver Clinic, there are 320 patients who have had a prescription written for hepatitis C medications but are waiting for approval before the prescription can be filled. Of these 320 patients, more than 50% are F2 or below and virtually all are Medicaid. This means that roughly 200 patients are in limbo waiting for their prescriptions to be approved and filled. These delays in treatment initiation are based on both the Medicaid protocol and recent changes to the Gilead patient assistant program.

Until wider access to treatment becomes available, providers can manage their F1 and F2 cases by making sure they are engaged in care and continue to monitor their labs so that they can be treated as soon as they become eligible. **It is important for patients to know their HCV status, even if they have early stage fibrosis, for the following reasons:**

1) **They can change harmful behaviors, such as excessive alcohol use and risky sharing of drug paraphernalia;**
2) **The cutoffs for who should receive antivirals may change; across the country payors are loosening criteria as new drugs enter the market and drive prices down;**
3) **Patient assistance programs are available for patients who have been denied an antiviral prescription; and**
4) **They may be able to access local clinical trials.**

Contributed by Michael Ninburg, Executive Director of the Hepatitis Education Project; John Scott, HCV-TAC Clinical Lead; and Elizabeth Barash, HCV-TAC Project Director

Recommended Laboratory Testing Procedures for HCV Underused

In May 2013, the Centers for Disease Control and Prevention (CDC) issued guidelines calling for routine use of FDA-approved nucleic acid testing (NAT) for detection of HCV RNA in serum or plasma from blood of at-risk patients who test reactive for HCV antibody (Ab). Several approaches to NAT were outlined, including collecting two blood specimens from a single venipuncture and conducting HCV NAT testing only for patients with a reactive HCV antibody test; use of the same sample of venipuncture blood used for initial HCV antibody testing for HCV NAT; and collection and testing of a follow-up specimen for patients with a reactive HCV antibody test.

A main reason for this guidance was evidence that many persons who are identified as reactive by an HCV antibody test might not subsequently be evaluated to determine if they have current HCV infection; therefore either of the first two options above are preferable to the last.

We examined data from the Washington State Department of Health system for Public Health Reporting of Electronic Data (PHRED) from January 2013 through the end of June 2015 to assess the current practices of NAT testing after a reactive Ab test. Here we refer to the first two options as reflex tests, since the patient did not need to return for a separate venipuncture. We determined whether an Ab and RNA test were run on specimens collected at the same venipuncture, and the amount of time elapsed between specimens collected for HCV Ab and RNA testing.

We found that reflex tests remain largely underused in clinical practice, accounting for only 40% of patients tested for both HCV Ab and RNA. There was no significant change in use of reflex tests over the evaluation period. The prevalence of reflex testing is overestimated because cases that had Ab screening only and no RNA testing were not included.

In addition to the 40% of patients that received reflex testing, our analysis found that approximately 38% of patients had a specimen collected for RNA testing within 28 days of their specimen collected for Ab testing. The delay between the specimens collected for HCV Ab and RNA testing was more than 28 days for 22% of patients.

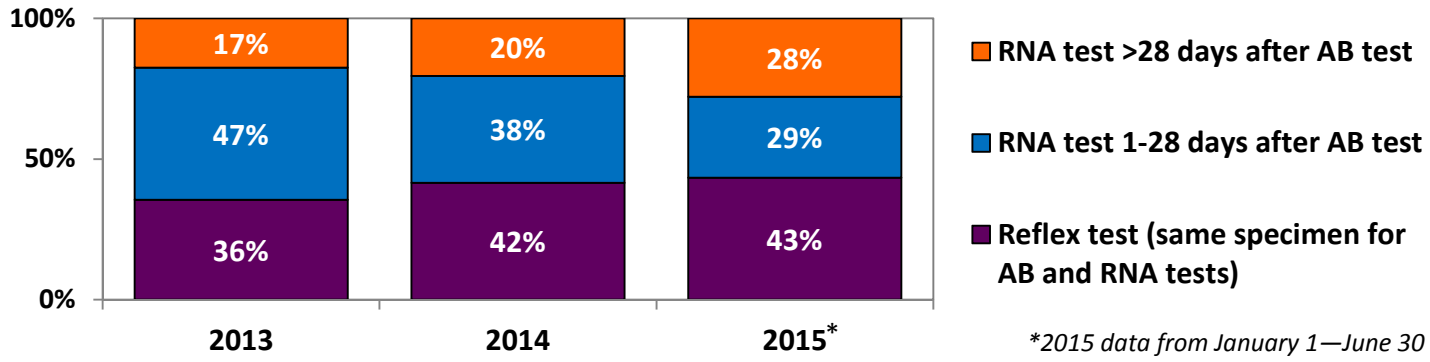
Among the 60% of patients that did not receive reflex testing, the median delay between the specimen collected for HCV Ab testing and the specimen collected for RNA testing was 16 days (interquartile range [IQR]: 7—57 days). However, among the 22% of patients with RNA specimen collection dates more than 28 days after Ab specimen collection, the median delay was 119.5 days (IQR: 50—257 days).

Health care providers and facilities should ensure that the default HCV screening order set used in practice is HCV Ab with reflex NAT testing. In addition, we strongly recommend that laboratory test menus make HCV Ab with reflex to quantitative or qualitative NAT testing the default HCV screening test with an opt out option for the rare instances when HCV Ab alone is desired.

We are working with King County laboratories to get a better understanding of current reflex testing practices, characterize challenges implementing reflex testing in different settings, and improve HCV testing practices.

Contributed by Atar Baer and Meaghan Munn

Timing of HCV RNA tests after positive HCV AB result among patients with both tests (n=1075), categorized by time from AB specimen collection to RNA specimen collection, January 2013 through June 2015



Project ECHO Updates

Project ECHO (Extension for Community Health Outcomes) is a weekly teleconference where primary care clinicians and those interested in caring for HCV patients can present their patient case histories to a multidisciplinary panel of experts at the University of Washington. In the past six months, we have welcomed providers from MultiCare (Dr. Abdul Siddiqui), HealthPoint (Dr. Matt Messerschmidt) and Neighborcare (Dr. John Olsen). In addition to case consultations, they hear a brief didactic and receive real-time assistance on issues as diverse as specialty guidelines, tips on how to access antivirals and care management. **If you are a provider in King County and want to participate in this mentorship, please contact Dr. John Scott at jdscott@uw.edu.**

Another great resource we recommend is HCV Online, a CDC/IAS funded website created at the University of Washington. We produced a streamlined and customized curriculum for primary care providers treating Hepatitis C (HCV) in King County from the larger 60+ chapter e-learning format (which remains available to all who want to delve deeper). The primary target audience is providers who are new to Project ECHO, although other providers are also encouraged to take advantage of the curriculum. **The course provides a basic, data driven primer for the epidemiology, diagnosis, staging, and treatment of HCV, as well as guidance on evaluating patients with HCV and how to obtain direct acting antivirals.** The curriculum itself combines text, PowerPoint lectures and videos that focus on complicated or confusing topics, and resources (such as templates for initial and return visits, lab monitoring flow sheets, and example letters to insurance carriers and pharmacies). Free CME credit is available to all participants to provide primary care providers with the tools necessary to treat uncomplicated HCV, particularly in conjunction with Project ECHO specialists.

Submitted by John Scott

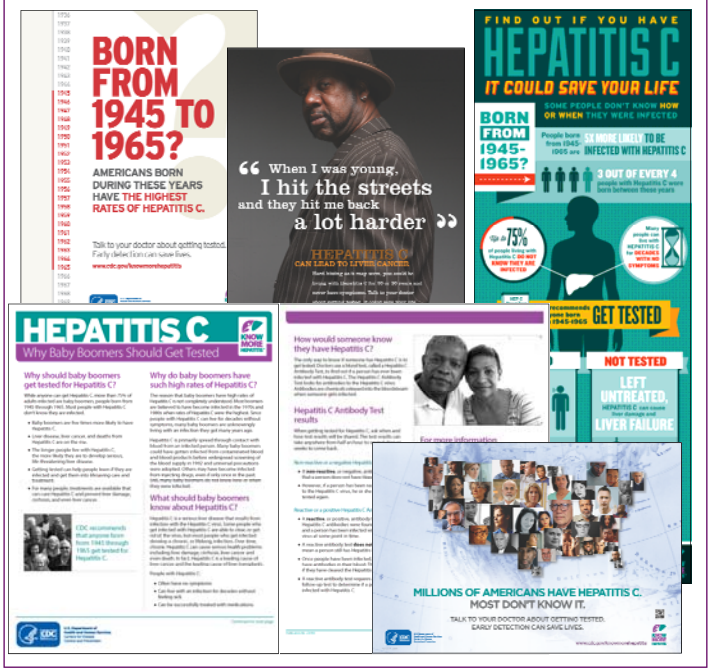
UNIVERSITY of WASHINGTON Project ECHO

Did you know?

KNOW MORE HEPATITIS™

Know More Hepatitis, the CDC's multi-media educational campaign to raise awareness of Hepatitis C, provides patient education materials including fact sheets, posters, infographics, videos, and more!

These materials can be displayed in waiting areas to encourage patients to initiate conversations about Hepatitis C or provided as a supplemental resource for those recently diagnosed with HCV. Materials can be found at:
cdc.gov/knowmorehepatitis/materials.htm



Next Meeting

Reminder: The next HCV Coalition meeting will be October 13, 2015 at 8 AM in Room 124

(Chinook Building, 401 5th Ave, Seattle)

We welcome your feedback.

Have ideas or suggestions for future issues?
Write us: elizabeth.barash@kingcounty.gov

Public Health Seattle & King County